

REMARKS

Review and reconsideration of the non-final Office Action mailed July 7, 2009 (hereinafter "Office Action"), is respectfully requested in view of the preceding amendments and the following remarks. This Amendment is accompanied by credit card authorization to charge the \$65 small entity fee for a one-month extension of time and the \$220 small entity fee for two additional independent claims in excess of three (*i.e.*, five total independent claims). Although no additional fees are believed due, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 14-1437.

At the time of the Office Action, claims 1, 2, 4 and 7-13 were pending, with claims 1-4 and 6-9 being drawn to an elected invention. In the Office Action, all claims were rejected under 35 U.S.C. §103(a) and 35 U.S.C. §112, first paragraph. By this Amendment, claim 1 is amended, claims 10-13 are cancelled, and claims 14-16 are added.

The amendments presented herein have been made solely to expedite prosecution of the instant application to allowance and should not be construed as an indication of Applicant's agreement with or acquiescence to the Examiner's position. Accordingly, Applicants expressly maintain the right to pursue broader subject matter through subsequent amendments, continuation or divisional applications, reexamination or reissue proceedings, and all other available means. The rejections are addressed in more detail below.

Claim Rejections – 35 U.S.C. §112, first paragraph

In the Office Action, claims 1, 2, 4 and 7-9 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action notes that alcohol, which can be included in the compositions disclosed in the specification, is often diluted in water. Thus, the Office Action requested clarification regarding the type of alcohol employed in the examples.

As an initial matter, Applicants note that claim 9 is not dependent on claim 1 and does not include any reference to an anhydrous composition. Accordingly, Applicants respectfully request that the rejection of claim 9 under 35 U.S.C. §112, first paragraph, be withdrawn.

With respect to the remaining claims, Applicants submit herewith a Declaration Under 37 C.F.R. §1.132 signed by co-inventors Giuseppe Maio on October 21, 2009 (hereinafter “Second Maio Declaration”). As explained in the Second Maio Declaration, alcohol was only used in Examples 1, 2, 9 and 10. Second Maio Declaration, Paragraph 3.

Where used, the alcohol used in the examples was ethanol with a degree of purity between 96% and 99.9%. *Id.* In addition, the amount of alcohol used in the examples ranged from 0.50% to 0.80%. Thus, the total amount of water in the examples would have been 4% or less of 0.80% or less, *i.e.*, **0.032% or less**. *Id.* In view of this miniscule amount of water, Mr. Maio asserts that a person of ordinary skill in the art would understand that the examples support the amended language that the claimed composition is a “substantially anhydrous composition.” Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 4 and 7-9 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, claims 1, 2, 4 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0059389 by Tournilhac *et al.* (hereafter “Tournilhac”) in view of U.S. Patent No. 5,580,550 by Gough *et al.* (hereafter “Gough”) and U.S. Patent No. 6,503,495 by Alwattari (hereinafter “Alwattari”). Applicants respectfully submit that this rejection adds nothing that should modify the unexpected results discussed in the previous response and previous Declaration, which the Examiner previously found persuasive.

Prior to addressing the cited art, Applicants wish to review the claimed cosmetic composition as set forth in amendment claim 1, which recites:

1. (Currently Amended) A cosmetic composition, suitable for application to facial skin, lips and eyelashes, consisting of:
 - from 2 to 25% of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range;
 - from 0.05 to 20% of disteardimonium hectorite;

from 1.1 to 90 % of isododecane;
the balance comprising conventional cosmetic excipients, colourants and additives, all percentages being by weight of the final composition, wherein said cosmetic composition is [[an]] a substantially anhydrous composition.

The claimed cosmetic composition suitable for application to facial skin, lips and eyelashes is a substantially anhydrous composition that consists of 2 to 25 wt-% polyisoprene produced by a comminuting and depolymerizing process, 0.05 to 20 wt-% disteardimonium hectorite, 1.1 to 90 wt-% isodecane, and conventional cosmetic excipients, colourants and additives. The polyisoprene is produced by step a), which comprises comminuting, *i.e.*, crushing or grinding, a solid polyisoprene with a molecular weight between 100,000 and 4,000,000, and step b), which comprises depolymerising the comminuted solid isoprene of step a). As will be evident, the particles produced by a comminuting process will have a substantially rougher surface morphology and more irregular shape than the spherical particles produced by conventional emulsion polymerization techniques. It is believed that, when combined with the other claimed ingredients, the rough surface morphology and irregular shape of the comminuted polyisoprene particles contributes to the properties of the claimed cosmetic compositions, which can be applied to the facial skin, the lips and the eyelashes to produce an unexpectedly stable, homogeneous, and long-lasting film.

Cosmetic products for make-up of face, lips, eyelashes, etc., often suffer from the drawback that, when they come into contact with fingers or clothing, they tend to smudge or soil these surface. In addition, in some cases the make-up can also appear to be not homogeneous.

In view of these existing issues, the technical problem underlines the present invention is that of providing a cosmetic composition which is stable, has high film-forming property and provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes (present application, page 1, lines 8-15 and on page 2, lines 15-18) and therefore does not smudge the surface to which it come into contact such as, for example, fingers or clothing (present application, on page 1, lines 8-15).

Such a problem is solved by the claimed substantially anhydrous cosmetic composition endowed with the combinative effect of the presence of the three specific components selected in

the claimed amounts, *i.e.*, 1) 2 to 25% of polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) 0.05 to 20% disteardimonium hectorite, and 3) 2.2 to 90% isododecane.

The advantageous effects of the combination of the above three elements have been extensively proved by means of experimental data shown in the First Maio Declaration submitted March 16, 2009 (hereinafter "First Maio Declaration"), which the Examiner found persuasive in order to overcome the objections of lack of inventive step in view of the previously cited prior art.

The first new cited prior art is Tournilhac, which discloses a cosmetic composition for coating keratin fibers, comprising a dispersion of particles comprising an at least one external supple phase and at least internal rigid phase, which is a functionalized crystalline or semicrystalline material having a first-order phase transition, of melting or combustion, of greater than 40°C. The at least one supple phase comprises at least one supple polymer having a glass transition temperature of less than or equal to 60°C. Of In addition, the supple polymer of the supple phase is at least partially attached by *chemical grafting* onto the rigid phase.

The composition of Tournilhac relates in particular to a mascara which is easily applied and gives good curling of the keratin fibers (Tournilhac, Paragraphs [0001] and [0003]). Among the above cited three essential components of the present cosmetic composition, Tournilhac cites polyisoprene embedded in a long list of possible supple polymers and the isododecane, as one of the possible lipophilic media wherein the multiphase particles may be dispersed in a second embodiment (Tournilhac, Paragraphs [0015]; [0050] and [0055]).

As far as the statement that Tournilhac's composition could be an anhydrous one, it is mentioned among other possible forms such as wax-in water, water in wax, oil-in water or water-in oil emulsion (Tournilhac, Paragraph [0189]).

Moreover, it is to be noted that the anhydrous form is not preferred. This is evident because the mascara A of Example 1 comprises nanocomposite aqueous dispersion and water (Tournilhac, Paragraph [0206]).

There is no disclosure in Tournilhac about the type of polyisoprene used and to the molecular weight thereof nor to the presence of any hectorite. However, Tournillac clearly relates to multiphase particles with an outer shell comprising the supple polymer and an internal core comprising the rigid phase (Tournilhac, Paragraph [0042]). As noted previously, the supple phase is *chemically grafted by the formation of covalent bonds* (Tournilhac, Paragraph [0032]), to the rigid phase. This configuration is produced using at least one emulsion or solution polymerization step, which would result in substantially smooth particles. (Tournilhac, Paragraphs [0046], [0047] & [0051]). As explained previously, and reiterated herein, contrary to the assertions of the Office Action, such smooth particles are not equivalent to the claimed comminuted particles because *smooth particles do not produce the unexpected results of the claimed compositions*.

Gough relates to a cosmetic composition comprising an emulsion, preferably an aqueous emulsion, including at least one cosmetic resin material, *e.g.*, a hydrocarbon resin such as polyisobutylene, made by direct emulsification of the resin without a solvent or carrier thereof. The direct emulsification may be achieved by a special mixing regime, with particular emulsifiers. The absence of solvent or carrier for the resin material would avoid product thinning and gives several manufacturing and processing advantages.

In particular, the Gough's cosmetic composition is a hair care composition such as a shampoo, wherein the hydrocarbon resin is preferably a per-alk(en)yl hydrocarbon material with a weight average molecular weight between 150 and 10,000,000 (Gough, Col. 3, lines 26-28).

Among the above cited three essential components of the present cosmetic composition, Gough only cites polyisoprene in the form of natural rubber (cis-1,4-polyisoprene) embedded in a long list of possible hydrocarbon resins (Gough, col. 3, lines 45-54). Thus, there is no motivation to specifically select polyisoprene from that list to produce the unexpected results of the claimed composition.

Moreover, it is to be noted that cosmetic composition of Gough is not anhydrous. In fact, the shampoo B comprises polyisobutylene and water (Gough, col. 9, lines 30-40).

Alwattari relates to oil-in-water mascara compositions comprising water-insoluble polymeric materials in the form of an aqueous emulsion, water soluble, film-forming polymers

and organophilic clays. Among the above cited three essential components of the present cosmetic composition, Alwattari only cites Bentone 38 (*i.e.*, disteardimonium hectorite) embed in a long list of possible organophilic clays (Alwattari, col. 5, lines 61-67 and col. 6, lines 1-19). Thus, there is no motivation to specifically select disteardimonium hectorite from that list in order to produce the unexpected results of the claimed composition.

In view of the foregoing, Applicants respectfully submit that a skilled person faced with the problem of the present invention, by reading the cited prior arts Tournilhac, Gough, and Alwattari would not find any hint or suggestion to select: 1) a polyisoprene obtainable as described in claim 1; 2) disteardimonium hectorite and 3) isododecane as three specific essential elements of an anhydrous cosmetic composition capable of solving the above problem. In the instant application, the claimed cosmetic composition unexpectedly demonstrates superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. The specific mixture of ingredients can only be produced by taking the cited references and (i) assuming polyisoprene particles produced by comminuting a solid polyisoprene and depolymerizing the polyisoprene is the same as generally disclosed polyisoprene grafted to a rigid phase (which is an erroneous assumption), and (ii) assuming that a person of skill in the art would (a) select disteardimonium hectorite from a long list of potential options, (b) select isododecane from a long list of potential options, (c) include these ingredients in the claimed amounts, and (d) decide to make a substantially anhydrous composition, despite the fact the preferred compositions include water. Through the data submitted herewith, Applicants have demonstrated that there is a substantial functional difference between spherical isoprene particles produced by emulsion/solution polymerization and the claimed irregularly shaped isoprene particles having a rough surface morphology. Furthermore, *despite the importance of the difference between a smooth surface and a rough surface morphology, the rejection fails to identify any reference disclosing irregularly shaped isoprene particles produced by a combination of comminuting and depolymerizing, much less the use of such particles in a cosmetic composition.* Thus, it is Applicants' position that the cited references fail to establish a *prima facie* case of obviousness.

Regardless of whether a *prima facie* case of obviousness has been established, Applicants note that the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. See *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); MPEP 716.02(a).II. & 2145.

Applicants respectfully submit that the combination of the cited references does not render the claimed cosmetic composition obvious because (1) the rejection fails to disclose each element of the claims, including the claimed isoprene particles produced by a comminuting and depolymerizing process, (2) the rejection relies on the assumption that several ingredients are interchangeable or equivalent when, in fact, they are not, and (3) because the claimed combination of ingredients produces unexpected results that are neither disclosed nor suggested by the cited references.

In order to demonstrated the unexpected results obtained by the claimed cosmetic composition, Applicants submit the attached Declaration Under 37 C.F.R. §1.132 by co-inventor Giuseppe Maio (hereinafter “First Maio Declaration”). As explained by Mr. Maio:

During my experiments, I have surprising[ly] found that the combination of 1) a polyisoprene (from 2 to 25% (w/w)) obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite (0.05 to 20% (w/w)) and 3) isododecane (from 1.1 to 90% (w/w)), the balance comprising conventional cosmetic excipients, colorants and additives, is critical in order to achieve an anhydrous cosmetic composition which is stable and provides for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

First Maio Declaration, Section 4.

Mr. Maio conducted extensive experimentation in order to arrive at the claimed cosmetic composition. From all of the compositions tested in these experiments, Mr. Maio has selected the following three in order to demonstrate the dramatic and unexpected improvements produced using the claimed ingredients. While additional details of compositions REM 513.32, REM 513.33, and REM 5123.34 can be found in the First Maio Declaration, Section 4, a summary of

these compositions is found below:

	REM 513.32	REM 513.33	REM 513.34
Polyisoprene	10.0 wt-% comminuted KRATON IR 310	10.0 wt-% comminuted KRATON IR 310	15.0 wt-% polyisoprene <u>latex</u> (KRATON IR401B)
Disteardimonium hectorite (BENTONE 38V)	6.0 wt-%	0.0 wt-%	6.0 wt-%
Isododecane	79.0 wt-%	85.0 wt-%	73.5 wt-%
Colourants	5 wt-%	5.0 wt-%	5 wt-%

The properties of these compositions were as follows:

REM 513.32

Aspect: Creamy fluid stable product endowed with high long lasting film properties.
Drying time after application: 3 minutes

REM 513.33

Aspect: Liquid unstable product, after 2 hours from its preparation the product shows an evident color phase separation and thus making the product not applicable.
Drying time after forced application; 6 minutes

RE 513.34

Aspect: Doughy unstable product, visually unhomogeneous and thus making the product not applicable.
Drying time after forced application: 10 minutes

In order to evaluate the aspect and the drying time, the unstable comparative products, *i.e.*, REM 513.33 and REM 513.34, have been made homogeneous. *See* First Maio Declaration, Section 4. Each of the compositions was evaluated using a transferability resistance assay and a saliva resistance assay.

The results of the Transferability Resistance Assay after 10 wipes were as follows:

REM 513.32	REM 513.33	REM 513.34
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No transfer	Very poor transfer	Poor transfer
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As noted by Mr. Maio:

[T]he films of the comparable product REM 513.34 deposited on the paper were visually unhomogeneous. As far as the comparable product REM 513.34 is concerned, it showed very evident colour streaks and its deposited film was easily removed by means of a finger wipe.

First Maio Declaration, Section 4.

The results of the Saliva Resistance Assay after 5 wipes, were as follows:

REM 513.32	REM 513.33	REM 513.34
Clean tampon, no colour transfer	Slightly colour dirty tampon, slight ring	Slightly colour dirty tampon, slight ring

Maio Declaration, Section 4.

In evaluating the experimental data, Mr. Maio explains:

From the above experimental data, it is evident that the combinative effect of the presence of the three specific components selected, *i.e.*, 1) the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite and 3) isododecane (REM 513.32) is essential in order to achieve a stable anhydrous cosmetic composition endowed with high film-forming property, which is easy to use and stable over a medium-long term and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown from the above data, only the invention product: (REM 513.32) is endowed with a homogeneous creamy fluid aspect, has good film-forming property and a short drying time after application which makes it easy to use.

Furthermore, from the data shown above, it is also evident that the invention product (REM 513.32) is also a stable product.

On the contrary, all the comparative products (REM 513.33 and REM 513.34) are unstable and with an unhomogeneous aspect and therefore

unsuitable for the preparation of a cosmetic composition for application to facial skin, lips and eyelashes.
First Maio Declaration, Section 5.

With this testing as background, it is Applicants position that the claimed cosmetic composition is not disclosed or suggested by any combination of the cited art and that the claimed cosmetic composition exhibits unexpected properties that are not disclosed or suggested by the cited references.

In *In re Chupp*, the claims at issue were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and com, but average herbicidal results for other crops. *See id.*, at 644. The prior art was a homolog of the claimed compound that differed from the claimed compound by a single methylene group (C=C), and was disclosed as being a selective herbicide for crops generally. Thus, the difference between the claimed compound and the prior art was a single methylene group and an unexpected improvement in herbicidal efficacy that was limited to two crops.

The Court noted that the claimed compound's "superior activity in com and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound was similar to the prior art and provided average selective herbicidal activity for many crops and poor herbicidal activity for others. *The Federal Circuit concluded that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a prima facie case of obviousness. See id.*, at 646.

The Federal Circuit nicely summarizes cases in this line by stating "*Obviousness cannot be predicated on what is not known at the time an invention is made,*" *In re Rijckaert*, 9 F.2d 1531, 1534 (Fed. Cir. 1993). In the instant case, it simply was not known that the claimed combination of the ingredients, in the claimed amounts, would unexpectedly exhibit superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. Accordingly, Applicants respectfully submit that the evidence of unexpected results submitted herewith is sufficient to overcome a *prima facie* case of obviousness, if one has been

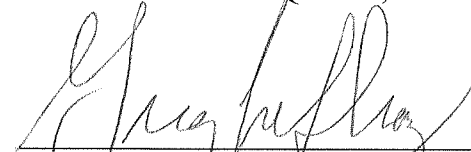
established (which Applicants would argue it has not). In view of the foregoing, Applicants respectfully request that the rejection based on the combination of Tournilhac, Gough and Alwattari be withdrawn.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned, Greg Lefkowitz (direct line 561-838-5229 x228), if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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